

**REMARKS/ARGUMENTS**

Upon entry of the present amendment, claims 1-8, 10, 12-19, 21 and 23 are pending and are under examination. Claims 1, 5-8, 10, 12-13, 16-19, 21 and 23 have been amended. Claims 9, 11, 20, 22 and 24-27 are canceled without prejudice or disclaimer.

Applicants believe no new matter is present in this or any other portion of the present amendment. Support for the amendments to the claims is found in the specification as originally filed. More particularly, support for the amendments to claims 1, 5, 7-8, 10, 12-13, 16, 18-19, 21 and 23 is found, *inter alia*, on page 10, line 34 bridging to page 11, line 5, and on page 11, lines 35-36, and on page 12, lines 29-35. Some amendments are merely to utilize the more standard Markush language "selected from the group consisting of."

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicants' remarks are presented in the order in which the corresponding issues were raised in the Office Action.

**I. FIRST REJECTION UNDER 35 U.S.C § 102(b)**

Claims 1-7, 11 and 12 stand rejected under 35 U.S.C § 102(b) as alleged anticipated by Commons et al. (U.S. Patent No. 5,439,915, "Commons"). The Examiner alleges that Commons teaches the composition of the present invention and while Commons does not specifically mention these compositions for the modulation of LXR function, the compositions would inherently possess LXR activity. Without acquiescing to the propriety of the rejection, and in view of the amendment to the claims, as well as the cancellation of claim 11, Applicants respectfully request reconsideration.

Applicants have amended claim 1 to set forth particular R<sup>1</sup> groups of the present invention. Claim 1 now recites that R<sup>1</sup> is selected from the group consisting of 1-(furan-2-yl)ethyl, 1-(pyridin-2-yl)ethyl, 1-(furan-2-yl)-2-propyl, 1-(2-pyridyl)-2-propyl, 1-(furanyl)isobutyl, 1-(3-pyridyl)isobutyl, 1-(pyridin-4-yl)ethyl, 1-(pyridin-4-yl)isobutyl, and 1-(3-furanyl)-3-but enyl.

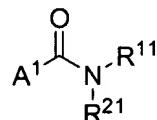
In contrast, Commons *fails to teach or suggest* any compounds having a R<sup>1</sup> group as set forth in amended claim 1. Accordingly, Applicants submit that the Commons reference fails to anticipate the present invention.

In view of the amendments, Applicants respectfully request that this rejection be withdrawn.

## II. SECOND REJECTION UNDER 35 U.S.C § 102(b)

Claim 13 stands rejected under 35 U.S.C. 102(b) as allegedly anticipated by Anderson et al. (WO99/44987, "Anderson"). The Examiner alleges that Anderson teaches compounds within the scope of Applicants' generic formula. Applicants have amended claim 13 to more particularly claim certain features of the present invention. To the extent the rejection is applicable to the amended claim, Applicants respectfully traverse the rejection.

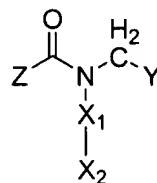
In particular, Applicants claim 13 is directed to compounds of Formula II.



Applicants' Formula II

Applicants have amended claim 13 to set forth particular R<sup>11</sup> groups of the present invention, now selected from 1-(furan-2-yl)ethyl, 1-(pyridin-2-yl)ethyl, 1-(furan-2-yl)-2-propyl, 1-(2-pyridyl)-2-propyl, 1-(furanyl)isobutyl, 1-(3-pyridyl)isobutyl, 1-(pyridin-4-yl)ethyl, 1-(pyridin-4-yl)isobutyl, 1-(2-furanyl)-3-butenyl and 1-(3-furanyl)-3-butenyl.

In contrast, Anderson discloses GnRH modulating agents as shown on pages 11-19 of WO99/44987 having the formula I:



Anderson's Formula I

According to Anderson, the compounds must be substituted with a basic group  $X_2$ , such as guanidinyl, amidinyl, acylamidinyl, azetidinyl and amino and that  $Y$  and  $X_1$  are both generally hydrophobic groups (see, page 4, line 24-26, Anderson).

In view of the amendment to claim 13, Applicants submit that the  $R^{11}$  substitutents of the invention are simply not taught or suggested by Anderson. For example,  $R^{11}$ , which might be considered as most nearly relating to the  $Y$  group of Anderson, has been amended to consist of 1-(furan-2-yl)ethyl, 1-(pyridin-2-yl)ethyl, 1-(furan-2-yl)-2-propyl, 1-(2-pyridyl)-2-propyl, 1-(furanyl)isobutyl, 1-(3-pyridyl)isobutyl, 1-(pyridin-4-yl)ethyl, 1-(pyridin-4-yl)isobutyl, 1-(2-furanyl)-3-butenyl or 1-(3-furanyl)-3-butenyl group. In each of the above  $R^{11}$  groups, a furanyl or pyridyl ring is attached through the 1-position of an alkyl moiety resulting in a "branched" substituent. Anderson discloses and claims compounds wherein  $Y$  is attached to the nitrogen of a carboxamide via methylene group rather than a branched alkyl. As a result, Anderson simply fails to teach or suggest any compounds in which the  $R^{11}$  group can be the various heteroaryl-alkyl groups as set forth in claim 13.

In view of the above, Applicants respectfully request reconsideration.

### III. REJECTION UNDER 35 U.S.C. § 103(a)

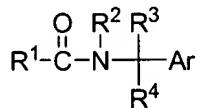
Claims 1-23 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious in view of Wetterich et al. (U.S. Patent No. 6,090,853, "Wetterich"). The Examiner alleges that Wetterich teaches a generic group of pharmaceutical compounds that embrace Applicants' instantly claimed compounds. The Examiner points to the compound in Table 28, page 17, of Wetterich and alleges that this compound differs from the instantly claimed compounds only in the nature of the substituent on the nitrogen atom (hydrogen vs. aryl) and that Wetterich teaches the equivalence of an aryl group and hydrogen. Thus the Examiner alleges, it would have been obvious to one skilled in the art to modify the genus of Wetterich to arrive at the instantly claimed compounds.

Applicants have canceled claims 9, 11, 20 and 22, which render the premise for the rejection of these claims moot. To the extent this rejection is applicable to the amended claims, Applicants respectfully traverse the rejection.

As set forth in M.P.E.P. § 2143:

[t]o establish a *prima facie* case of obviousness, *three* basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Turning first to a discussion of Wetterich, Applicants note that Wetterich discloses amide compounds of Formula I that have fungicidal activity.

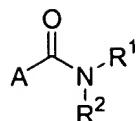


Wetterich's Formula I

wherein R<sup>1</sup> is unsubstituted or substituted bicycloalkyl, tricycloalkyl or bicycloalkenyl; R<sup>2</sup>, R<sup>3</sup> and R<sup>4</sup> are mutually independently hydrogen, or substituted or unsubstituted: alkyl, cycloalkyl, cycloalkenyl or heterocyclyl; Ar is unsubstituted or substituted aryl or hetaryl (see Abstract).

Despite the broad disclosure set forth by Wetterich, Applicants respectfully note that no compounds were prepared and evaluated other than those wherein R<sup>2</sup> is H. This feature was apparently not lost on the Patent Office as the issued claims are limited to Wetterich's formula I in which R<sup>2</sup> and R<sup>3</sup> are both hydrogen!

In contrast to Wetterich, Applicants disclose and claim compounds having two substituents on the amide nitrogen. In particular, Applicants teach amides of Formula I as agents for the treatment of, for example, atherosclerosis:



Applicants' Formula I

wherein A is (C<sub>5</sub>-C<sub>18</sub>)alkyl; R<sup>1</sup> is 1-(furan-2-yl)ethyl, 1-(pyridin-2-yl)ethyl, 1-(furan-2-yl)-2-propyl, 1-(2-pyridyl)-2-propyl, 1-(furanyl)isobutyl, 1-(3-pyridyl)isobutyl, 1-(pyridin-4-yl)ethyl, 1-(pyridin-4-yl)isobutyl, 1-(2-furanyl)-3-butenyl or 1-(3-furanyl)-3-butenyl group; and R<sup>2</sup> is selected from aryl, heteroaryl, aryl(C<sub>1</sub>-C<sub>8</sub>)alkyl, heteroaryl(C<sub>1</sub>-C<sub>8</sub>)alkyl, aryl(C<sub>2</sub>-C<sub>8</sub>)heteroalkyl and heteroaryl(C<sub>2</sub>-C<sub>8</sub>)heteroalkyl.

Applicants' present claims have limited the R<sup>1</sup> group, which most nearly relates to Wetterich's -C(R<sup>3</sup>)(R<sup>4</sup>)Ar group, to specific heteroaryl(alkyl)groups. In contrast, although Wetterich broadly discloses that his "Ar" group can be any number of aryl and hetaryl groups, Wetterich **fails** to provide exemplification for any compound other than ones wherein **Ar is phenyl** (see, Tables 1-29, Wetterich).

Further distinctions in the inventions can be seen by comparing R<sup>2</sup> groups. While the R<sup>2</sup> group of Applicants' formula I, which coincidentally is compared to the R<sup>2</sup> group in Wetterich, can be various heteroaryl, aryl, (heteroaryl)alkyl or arylalkyl groups, Wetterich **fails** to disclose a single compound in which R<sup>2</sup> is anything other than hydrogen. Moreover, Wetterich fails to disclose *any* method of preparation of compounds wherein R<sup>2</sup> is other than hydrogen.

Applicants respectfully submit that the Examiner's assertion that for R<sup>2</sup>, Wetterich teaches that "hydrogen" atom is equivalent to an "aryl" group is unsubstantiated. As Wetterich has only provided working examples of compounds in which R<sup>2</sup> is hydrogen, Applicants submit that Wetterich's disclosure does not support, whether through a showing of working examples, or through teachings in the specification itself, that a compound having R<sup>2</sup> is hydrogen would be functionally equivalent to a compound having R<sup>2</sup> as a group such as aryl or aryl(C<sub>1</sub>-C<sub>8</sub>)alkyl, for example.

In summary, Wetterich simply *does not teach or suggest* the claimed features of Applicants' invention. Applicants submit that Wetterich fails to teach or suggest any compounds

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Amdt. dated December 19, 2003  
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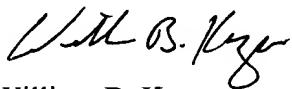
in which the equivalent R<sup>1</sup> group can be a member of a defined set of specific heteroaryl groups as set forth by Applicants. Nor does Wetterich teach or suggest any compounds in which the R<sup>2</sup> group can be anything other than hydrogen. Thus Applicants submit that the limited teaching of Wetterich would also fail to motivate one skilled in the art to prepare any compounds other than ones in which R<sup>2</sup> is H and Ar is phenyl. In the absence of any direction in Wetterich, Applicants submit that Wetterich does not teach or suggest the present invention and respectfully request that the present rejection be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5015.

Respectfully submitted,



William B. Kezer  
Reg. No. 37,369

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, 8<sup>th</sup> Floor  
San Francisco, California 94111-3834  
Tel: 925-472-5000  
Fax: 415-576-0300  
WBK:sc  
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